UNITED STATES DISTRICT COURT
SOUTHERN DISTICT OF NEW YORK

QUINTESSA HUEY, Individually and on behalf of All Others Similarly Situated, Plaintiff, vs. ANAVEX LIFE SCIENCES CORPORATION and CHRISTOPHER U. MISSLING, Defendants.	Case No.: 1:24-cv-01910-CM

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT

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I. INTRODUCTION

Anavex Life Sciences Corporation is a biopharmaceutical company with a checkered past. Without any FDA-approved drugs and no commercial revenue streams, Defendants have made a habit out of raising money from retail investors through private placements and at-the-market offerings fueled by flashy "pump-and-dump" style promotional press releases. This has landed the company in trouble over the years with trading halts and regulatory investigations both in Canada and here in the United States. Not to be deterred, Anavex and its CEO Christopher Missling have managed to raise $250 million over the past five years with nearly a quarter of that in the last two years alone—more than enough to fund the company's operations and Missling's multi-million dollar compensation packages.

This case focuses on Defendants' most recent ploy. Missling launched a series of clinical trials to test Anavex's supposed lead drug candidate, ANAVEX 2-73, as a treatment for Rett Syndrome. Clinical drug trials are designed to test the safety and efficacy of a drug, or the "clinical benefit," among a certain patient population. The trials measure the effectiveness of the drug using a "primary endpoint" measurement. In the case of Rett Syndrome, the FDA required a particular "primary endpoint" for clinical trials referred to as RSBQ/CGI-I (which stands for the Rett Syndrome Behavior Questionnaire combined with the Clinical Global Impression-Improvement scale). Anavex knew that the FDA required this "primary endpoint" but told analysts and investors it could use a variation of the RSBQ endpoint that incorporated an Area Under the Curve measurement or RSBQ-AUC.

This was a big deal. Those with experience in the field of Rett Syndrome testing immediately appreciated the value and potential upside associated with Anavex being able to use RSBQ-AUC instead of RSBQ/CGI-I. RSBQ/CGI-I requires a sustained improvement in health to

establish efficacy whereas RSBQ-AUC takes a more lenient approach by effectively requiring only some improvement at some point during the clinical trial. Put differently, so long as the patient shows improvement for some period of time during the trial, RSBQ-AUC will produce positive results even if the patient is just as sick (or sicker) at the end of the trial than she was at the beginning. Consequently, when Missling reported clinical data using the RSBQ-AUC measurement, analysts honed in on this and did their best to verify whether Anavex was in fact going to be allowed to use that "primary endpoint" instead of RSBQ/CGI-I.

Defendants spent nearly the entire Class Period "hiding the ball" as to which endpoint they would use, never telling anyone that the FDA had in fact told them time and again that RSBQ/CGI-I was the "primary endpoint" they needed to use for any "pivotal" trial intended to support a new drug application. The truth only started to emerge when, in response to persistent questioning from investment analysts during an earnings conference call, Missling finally confirmed that Anavex's latest clinical trial (the EXCELLENCE trial) would not be using RSBQ-AUC. However, at that, Missling lied about the reasons why and continued to conceal the reality that the FDA would not allow RSBQ-AUC data to support a regulatory approval package. When Defendants ultimately revealed the EXCELLENCE trial's results at the end of the Class Period, it became evident why Missling had for so long pushed the lie that they would be able to use RSBQ-AUC—the results under the correct RSBQ/CGI-I endpoint showed that ANAVEX 2-73 had failed.

Plaintiffs allege violations under the Securities Exchange Act of 1934 as modified by the Private Securities Litigation Reform Act of 1995. 15 U.S.C. §78u-4 ("PSLRA"). While the PSLRA carries special pleading standards for fraud claims, these standards are not meant to create a near-impossible hurdle for plaintiffs to overcome, as Defendants would lead this Court to believe. The PSLRA does not turn the motion to dismiss into a trial by papers. All factual allegations in the

complaint are still required to be accepted as true and common-sense inferences should not be disregarded. *See Altimeo Asset Mgmt. v. Qihoo 360 Tech. Co. Ltd.*, 19 F.4th 145, 150 (2d Cir. 2021) (emphasizing that courts "must be careful not to mistake heightened pleading standards for impossible ones"). Notwithstanding, Defendants primarily argue that Plaintiff is wrong on the facts and that the FDA never told Anavex it needed to use RSBQ/CGI-I as its "primary endpoint" measurement. This argument is not only procedurally improper (for arguing facts at the pleading stage) but it also is contradicted by statements during the Class Period in which Defendants acknowledge receipt of the FDA's "guidance," that the standards were "very clear," and that they could not use a "responder" style analysis such as the RSBQ-AUC measurement.

Alternatively, Defendants argue that no reasonable investor could have been misled about the endpoint Anavex was using in the EXCELLENCE trial because they "accurately and repeatedly" disclosed it throughout the Class Period. Missling's public statements about the EXCELLENCE endpoint were about as clear as mud, and intentionally so. He told analysts that EXCELLENCE would use RSBQ-AUC on at least several occasions, told them to disregard contrary statements posted on ClinicalTrials.gov (which, by the way, risked subjecting Anavex to civil money penalties under federal regulations), and never told anyone that RSBQ-AUC had been rejected by the FDA as the "primary endpoint" for the EXCELLENCE trial. Simply put, the record does not support the sort of "truth-on-the-market" defense Defendants are trying to mount.

For these reasons and as explained in further detail below, Plaintiff respectfully requests that the Court deny Defendants' motion to dismiss in its entirety.

II. BACKGROUND FACTS

A. Anavex Proposes ANAVEX 2-73 as a Treatment for Rett Syndrome.

Anavex's lead drug candidate is, and has always been, ANAVEX 2-73. ¶17. Despite its many supposed potential uses (*e.g.*, Alzheimer's, Parkinson's, and other central nervous system diseases), Anavex has never successfully tested the drug let alone obtained FDA approval to market it. ¶17. In turn, Anavex has historically relied on private stock sales and at-the-market offerings to generate cash. ¶18. Stock sales, of course, are meaningless unless the stock has some value in the market. Thus, Anavex has consistently taken steps to maintain an elevated trading price for its shares by using a combination of paid promoters and promotional marketing, *i.e.*, misleading press release. ¶¶19, 112-13.

This case focuses on Anavex's latest gambit involving ANAVEX 2-73's application to Rett Syndrome. In 2016, Anavex announced "positive preclinical data" and secured Orphan Drug Designation from the FDA, which provides certain benefits to the manufacturer or sponsor such as tax credits and marketing exclusivity for a period of time. ¶22. In 2017, Anavex obtained money (in the form of a grant) from the International Rett Syndrome Foundation to cover clinical trial costs for a Phase 2 trial and, in 2018, received FDA approval to commence testing. ¶¶23-24.

Analysts responded favorably to Anavex's Rett Syndrome initiative given that it opened the door to a new pathway towards commercialization and revenue. ¶25; *see also* ¶¶29, 33 (subsequent analyst reports in response to later announcements). Anavex seized on the opportunity and over the course of just nine months commenced three new clinical trials for ANAVEX 2-73 in Rett Syndrome: (1) a Phase 2 trial in March 2019 (¶24); (2) a second Phase 2 trial in June 2019 (the AVATAR trial) (¶26); and (3) a Phase 2/3 trial in September 2019 (the EXCELLENCE trial) (¶30). None of these trials produced successful results yet in each instance, Defendants claimed

otherwise before finally abandoning the Rett Syndrome cause at the end of the Class Period in favor of redirecting investor attention back towards Alzheimer's disease. ¶¶7-8, 113. In the interim though, Defendants used the hype around Rett Syndrome to raise $50 million through at-the-market offerings (with Lincoln Park Capital and other brokers) and pay Missling a compensation package worth $10.5 million. ¶¶18, 20-21.

B. The FDA Requires RSBQ/CGI-I for Rett Syndrome Trials.

By the time Anavex commenced its first Phase 2 trial in March 2019, the FDA had already specified the "primary endpoint" required for a Rett Syndrome clinical trial. ¶4. Neuren Pharmaceuticals started developing DAYBUE in 2012 and had completed two Phase 2 trials for the drug by the end of 2016. ¶34. On October 12, 2017, Neuren Pharmaceuticals held its "end-of-phase 2" meeting with the FDA, which is a formal meeting conducted between a drug sponsor and the FDA in advance of moving on to Phase 3. ¶35. The purpose of the meeting is to obtain the FDA's approval for a Phase 3 trial protocol that, if completed successfully, will result in the approval of a new drug application. ¶35. During the "end-of-phase 2" meeting, the FDA directed Neuren Pharmaceuticals to use as its primary endpoint the Rett Syndrome Behavior Questionnaire (RSBQ) combined with the Clinical Global Impression-Improvement scale (CGI-I) or, put differently, "RSBQ anchored with CGI-I" (*i.e.*, RSBQ/CGI-I). ¶36.

In 2018, after the "end-of-phase 2" meeting, Neuren Pharmaceuticals licensed DAYBUE to another drug company, Acadia Pharmaceuticals. Acadia Pharmaceuticals then conducted the Phase 3 trial from October 2019 to December 2021 (the LAVENDER trial). ¶¶38, 40. The LAVENDER trial was successful, and Acadia Pharmaceuticals received marketing approval from the FDA in March 2023. ¶¶40-41.

C. The FDA's RSBQ/CGI-I Is *Not* the Same as Anavex's RSBQ-AUC.

Anavex did not use the FDA-approved RSBQ/CGI-I "primary endpoint" in its Rett Syndrome clinical trials. Instead, Defendants told investors that they could use a variation of the RSBQ endpoint that incorporated an Area Under the Curve measurement (RSBQ-AUC). ¶5. The difference between RSBQ/CGI-I and RSBQ-AUC is vastly important when measuring the efficacy of a Rett Syndrome treatment. ¶6.

RSBQ is a questionnaire assessment administered to a Rett Syndrome patient by her caregiver. ¶55. Efficacy is measured by comparing the patient's baseline score (pre-treatment) to her score at the end of the study (post-treatment). CGI-I is a similar assessment but completed by the patient's clinician to assess how much the patient's illness has improved or worsened. ¶55. Importantly, both measures (RSBQ and CGI-I) compare final end-of-treatment scores against baseline scores to determine efficacy. ¶55. RSBQ anchored with CGI-I (*i.e.*, using the measures as a cross-check) is the FDA-approved endpoint for Rett Syndrome clinical trials. ¶55.

Defendants' RSBQ-AUC deviated materially from what the FDA had approved. Instead of comparing before and after measurements, RSBQ-AUC measured a patient's "response" throughout the trial ultimately generating a sum of patient scores. ¶56. Consequently, RSBQ-AUC allowed Defendants to claim success so long as the patient exhibited improvement at some point during the trial, even if the last measurement was the same or worse than the initial reading. ¶56.[1] The scientific community has explicitly rejected RSBQ-AUC for this exact reason. For example, Dr. Daniel Tarquinio, a "key opinion leader" in the Rett Syndrome field who founded the Center

[1] To illustrate, if the patient's baseline and final scores were both a measure of "1", the RSBQ-AUC measurement would still show successful treatment as long as the patient scored greater than "1" at some point during the trial (for example, if she scored "50" even if only for a day or two). By comparison, RSBQ/CGI-I requires the patient to demonstrate a sustained improvement between baseline and final measurement.

for Rare Neurological Diseases, referred to RSBQ-AUC as "artificial" and not capable of serving as an acceptable "primary endpoint." ¶57.

D. Defendants Knew RSBQ-AUC Was Not Allowed.

The FDA would not accept RSBQ-AUC as an endpoint and Defendants knew it. ¶58. By the start of the Class Period on February 1, 2022, the FDA had already identified RSBQ/CGI-I as the accepted "primary endpoint" for a Rett Syndrome trial and had told Defendants repeatedly to use it as the "primary endpoint" in clinical trials. ¶58. Indeed, the FDA instructed Anavex to use RSBQ/CGI-I when discussing and/or approving: Anavex's clinical trial plans and investigational new drug applications for the Phase 2, AVATAR, and EXCELLENCE trials in March, June, and September 2019, respectively; ANAVEX 2-73's Rare Pediatric Disease designation in November 2019; Anavex's application for Fast Track status in February 2020; and subsequently thereafter when commenting on Anavex's clinical trial designs and regulatory approval packages in February 2023. ¶58.

Without question, the FDA communicated the RSBQ/CGI-I requirement to Defendants. Anavex met with the FDA to discuss its clinical trial program for ANAVEX 2-73 for Rett Syndrome between December 2017 and February 2018. ¶59. The FDA provided feedback on the proposed study protocols, including the "primary endpoints" that Anavex intended to use. ¶59. The FDA's feedback on the endpoints was required by regulation as part of the "pre-IND" meeting. ¶59 (citing 21 C.F.R. 312.22). Given that the FDA had already selected RSBQ/CGI-I as the required "primary endpoint" for Rett Syndrome trials (*i.e.*, during the "end-of-phase 2" meeting for DAYBUE in October 2017), Anavex knew by February 2018 at the latest that RSBQ-AUC

would not be accepted as a "primary endpoint" for any "pivotal" study. ¶59.[2] Furthermore, given that Anavex received Fast Track status for ANAVEX 2-73, the FDA was required to give Anavex "more intensive guidance on an efficient drug development program with increased interactions and communications with the FDA," thereby further ensuring that Defendants knew RSBQ-AUC would not be allowed as a "primary endpoint." ¶59 (quoting U.S. FOOD & DRUG ADMIN., BEST PRACTICES FOR COMMUNICATION BETWEEN IND SPONSORS AND FDA DURING DRUG DEVELOPMENT: GUIDANCE FOR INDUSTRY AND REVIEW STAFF (2017)).

E. Defendants Tell Investors They Can Use RSBQ-AUC.

Had Anavex been allowed to use RSBQ-AUC for its "primary endpoint," Defendants would have been able to show a "clinical benefit" with weaker data (thereby increasing ANAVEX 2-73's prospects for approval). *See* ¶83 (Missling admitting that "anchor-based method . . . raised the bar for us, for the drug"). This is because RSBQ-AUC measured patient "responses" throughout the trial instead of just at the beginning and end, thereby allowing Anavex to claim success in potentially more ways. ¶¶56-57. Analysts appreciated the leeway inherent in Anavex's RSBQ-AUC endpoint and accordingly focused in on it when Defendants discussed it during the Class Period. For example, on February 1, 2022, a BTIG investment analyst asked Missling whether the EXCELLENCE study would use the same RSBQ-AUC endpoint that was used in the AVATAR trial; Missling responded that "the EXCELLENCE study will use the same endpoint . . . because . . . it is just the preference of the FDA." ¶75. This was false or, at the very least, misleading because Missling knew the EXCELLENCE trial could not serve as a "pivotal" trial for ANAVEX 2-73 unless it used RSBQ/CGI-I as its "primary endpoint," thereby creating the false

[2] A "pivotal" study refers to a clinical trial intended to be used as primary support for a new drug application with the FDA. ¶79.

impression that Anavex could rely on RSBQ-AUC data when seeking approval for ANAVEX 2-73. ¶76. The statement was also false because Missling unquestionably knew by this point in time that the FDA's "preference" was RSBQ/CGI-I and not RSBQ-AUC. ¶77.

Defendants continued on in this fashion for several months as the EXCELLENCE trial played out, claiming time and again in multiple ways that the FDA had approved their RSBQ-AUC measure. *E.g.*, ¶83 (Feb. 9, 2022: "the guidelines of the FDA guidance are really specific"); ¶86 (May 10, 2022: "that is the endpoint which we will also propose for the EXCELLENCE study. That is correct. It's consistent with the AVATAR study."); ¶89 (Nov. 28, 2022: "both endpoints are critical"); ¶94 (Feb. 2, 2023: "In communication with the FDA, we received their input on the endpoints, which were utilized in this study."). Even when Defendants reluctantly revealed halfway through the Class Period that the EXCELLENCE trial would not use RSBQ-AUC, they refused to disavow it. *See, e.g.*, ¶97 (Feb. 7, 2023: "Because the study is large enough that it can carry the signal by itself without AUC"); ¶101 (Aug. 8, 2023: discussing results from "drug effect model" analysis resembling RSBQ-AUC). This prevented analysts from writing off the value Defendants previously placed on the AVATAR trial's RSBQ-AUC results. By concealing the impropriety of the RSBQ-AUC analysis and the overall weakness of ANAVEX 2-73's data, Defendants successfully created and maintained a false sense of hope among investors. ¶103. Defendants fooled the analysts too who widely reported favorably on Anavex's clinical trial progress and claimed ANAVEX 2-73 was on track for regulatory approval in 2024. ¶103.

Investors ultimately discovered the truth at the end of the Class Period on January 2, 2024 when, six months after completing the EXCELLENCE trial, Defendants finally reported topline data. ¶62. In pertinent part, Defendants revealed that ANAVEX 2-73 did not meet the RSBQ/CGI-I "primary endpoint" required by the FDA. ¶63. Moreover, in a failed attempt to provide investors

with some good news, Defendants provided an "ad hoc" analysis of the data that supposedly demonstrated positive findings. ¶65. This "ad hoc" analysis, however, set off alarm bells given that it relied on a modified intent-to-treat analysis that inexplicably omitted 15 patients from the analysis, which experts perceived as an attempt to manipulate the trial data. ¶¶66-70.

Anavex's stock price immediately fell in response to the EXCELLENCE trial results. Analysts lowered their price targets on the basis that ANAVEX 2-73 was no longer a viable candidate for "regulatory approval" and would likely need to conduct an additional trial if Anavex was still interested in developing a treatment for Rett Syndrome. ¶71. Investors who purchased shares during the Class Period sustained significant damages as Anavex's stock price fell from $9.31 per share to $6.045 per share in the span of just one trading day. ¶72.

III. LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Employees' Ret. Sys. v. Blanford*, 794 F.3d 297, 304 (2d Cir. 2015) (internal quotations omitted). When evaluating the complaint, the court must "draw[] all reasonable inferences in the plaintiff's favor." *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 161 (2d Cir. 2000). The allegations in the complaint, along with the inferences drawn therefrom, need only "'raise a right to relief above the speculative level.'" *ATSI Communs., Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1965 (2007)). Once a claim has been adequately stated, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Id.*

IV. ARGUMENT

A. Defendants Misrepresented the FDA's Acceptance of RSBQ-AUC and Their Ability to Rely on RSBQ-AUC Data.

Under Rule 9(b) and the PSLRA, a plaintiff must specify the alleged statements, "identify the speaker, state where and when the statements were made, and explain why the statements were fraudulent." *In re Vivendi Universal, S.A. Sec. Litig.*, 381 F. Supp. 2d 158, 184 (S.D.N.Y. 2003). To do this, a plaintiff need only plead facts "sufficient to support a reasonable belief as to the misleading nature of the statement or omission." *Sharette v. Credit Suisse Int'l*, 127 F. Supp. 3d 60, 89 (S.D.N.Y. 2015). The Complaint readily satisfies this standard.

On February 1, 2022, Anavex hosted a conference call to discuss the AVATAR trial results, which had attracted significant analyst attention due to what many perceived was a last-minute sleight of hand from Defendants. ¶42. Specifically, just two weeks before the February 1 call, Anavex upgraded the AVATAR trial from a Phase 2 trial to a Phase 3 trial on ClinicalTrials.gov and changed its "primary endpoint" to RSBQ-AUC. ¶¶47-49, 51. The change was significant given that there was no mention of a "primary endpoint" change at any point prior despite nearly a dozen updates to the protocol on ClinicalTrials.gov and multiple opportunities to discuss such a change during conference calls and presentations over the course of the three-year trial. ¶¶43-46. Consequently, analysts questioned the change, whether it had been approved by the FDA, and if RSBQ-AUC would now be the "primary endpoint" used in EXCELLENCE going forward. ¶¶52-54 (analysts questioning the strength and reliability of the AVATAR trial's data); *see also* ¶60 (15% decline in stock price following change in "primary endpoint").

Analysts were hyper-focused on the change in endpoints given what it meant for the EXCELLENCE study going forward. Thus, when Missling opened the call for questioning,

analysts asked point-blank whether RSBQ-AUC was the new "primary endpoint" and if it had been endorsed by the FDA, as excerpted below:

> <Yun Zhong, BTIG, LLC, Research Division – Analyst>: So one question -- so follow-up question on the endpoint. And I assume that when you report top line data from the EXCELLENCE study, it will be RSBQ AUC as well? And do you have to go back to the U.S. Phase II study to reanalyze the data using AUC versus the -- as compared to the original RSBQ to make everything consistent?
>
> <Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Good question. Thank you. So that's right, ***the EXCELLENCE study will use the same endpoint*** . . . . because it's just described, ***it is just the preference of the FDA***.

¶75 (emphasis added); *see also* ¶¶81 (representing that EXCELLENCE would use RSBQ-AUC).

This was not true. RSBQ-AUC was not "the preference of the FDA" because, in fact, the FDA had already identified RSBQ/CGI-I as the required "primary endpoint" in Rett Syndrome trials. ¶77. Missling knew this too; the FDA told him on several occasions throughout ANAVEX 2-73's development process. ¶76 (listing FDA meetings between 2018 and 2020). Thus, Missling knew that ANAVEX 2-73 would not be able to secure approval with RSBQ-AUC results, meaning that the EXCELLENCE trial would ultimately not use it as a "primary endpoint" measure. ¶76. Relatedly, Missling also knew that the AVATAR trial (which now relied on RSBQ-AUC) was also ineligible to serve as a "pivotal" trial in support of a new drug application for ANAVEX 2-73. ¶¶78-79 (Missling claiming AVATAR trial can support "data package" for approval).

Plaintiff's theory of falsity is supported by any number of cases in which a regulatory agency takes a position or acts in some way that contradicts or harms a company's business, yet the company's executives assure investors everything is fine and act as if nothing is wrong. For example, in *Christine Asia Co. v. Ma*, 718 F. App'x 20 (2d Cir. 2017), a government agency told the defendants (who included the online e-commerce company Alibaba Group Holding Limited) that they needed to cease selling "counterfeit goods" or risk being subjected to "huge repeating

fines." *Id*. at 22-23. According to the court, the threat posed to investors was sufficiently material to warrant disclosure as the outcome in either event would have negatively affected Alibaba's earnings and operations. *Id*. Moreover, in reaching this conclusion, the court held it was "required" to "credit[] [the plaintiff's] proffered reasonable inference[s]" over the defendants' opposing arguments at the motion to dismiss stage. *Id*. at 23. The edict against selling counterfeit goods is analogous to the restriction against relying on RSBQ-AUC; both warranted disclosure. *See also Noto v. 22nd Century Grp., Inc.*, 35 F.4th 95, 105-06 (2d Cir. 2022) (statements misleading where defendants concealed SEC investigation into company's accounting controls); *In re Didi Glob. Inc. Sec. Litig.*, No. 21-cv-05807 (LAK), 2024 U.S. Dist. LEXIS 46461, *13-14 (S.D.N.Y. Mar. 14, 2024) (concealing regulator's "directive" or "suggestion" to postpone IPO was material adverse information that should have been disclosed); *In re Y-Mabs Therapeutics, Inc. Sec. Litig.*, No. 23-cv-431 (AS), 2024 U.S. Dist. LEXIS 19499, *27-28 (S.D.N.Y. Feb. 5, 2024) (defendants misled investors by providing false information about "feedback and guidance" from FDA); *Skiadas v. Acer Therapeutics Inc.*, No. 1:19-cv-6137-GHW, 2020 U.S. Dist. LEXIS 105814, *27-28 (S.D.N.Y. June 16, 2020) (statements about clinical development program false where FDA had not agreed to accept trial data without further studies).

Defendants continued their lie throughout the Class Period, perpetuating the false impression that the FDA would allow RSBQ-AUC data to support a regulatory approval package for ANAVEX 2-73. *See*, *e.g.*, ¶¶78, 84, 86, 89, 92, 95, 97, 100. At minimum, Defendants' statements misled investors given what they had been told previously about the necessity of RSBQ/CGI-I data, which is all that is necessary for them to be actionable. *See McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990) (disclosures required under the securities laws are "measured not by literal truth," but based on whether they "would have mislead

a reasonable investor"); *see also Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 609 (4th Cir. 2015) (statement that "FDA had 'agreed' that [defendant] could submit its new drug application . . . 'without the need for any further efficacy studies'" was actionable even if literally true where company did not disclose that another study was required for approval); *In re Innocoll Holdings Pub. Co. Sec. Litig.*, No. 17-341, 2020 U.S. Dist. LEXIS 51666, *47 (E.D. Pa. Mar. 24, 2020) ("Defendants inappropriately focus on the literal accuracy of the statements instead of whether the statements accurately informed rather than misled prospective buyers.").

Defendants' chief argument in response to these allegations is that the FDA did not have a "requirement" to use RSBQ/CGI-I as an endpoint. Defs. Br. at 7-8. This argument directly contradicts Plaintiff's well-pleaded allegations, which are to be accepted as true and "credit[ed]" over any competing narrative from Defendants. *See Christine Asia*, 718 F. App'x at 23. When the FDA told Neuren Pharmaceuticals to use RSBQ/CGI-I as its "primary endpoint" for the LAVENDER study, that represented the FDA's position on Rett Syndrome trial protocol for all clinical trials going forward. ¶¶35-36. Defendants may quibble over how stern the FDA was when it "urged, suggest[ed], [or] pressure[d]" Anavex to use RSBQ/CGI-I, but "[t]he semantic distinction [Defendants] draw[] is not a meaningful one in this context. It is reasonable to infer . . . that an urge, suggestion, or pressure from the [FDA] is tantamount to a directive. In any case, plaintiffs allege that the [FDA] 'directed' [Anavex] to [use RSBQ/CGI-I], notwithstanding other allegations that characterized the interaction between the regulator and company slightly differently." *In re Didi Glob. Inc. Sec. Litig.*, 2024 U.S. Dist. LEXIS 46461, at *13-14.

Defendants' argument is also contradicted by the things they said and did in real life at the time. Though they claim now that RSBQ/CGI-I was never a "requirement," with the benefit of hindsight it becomes apparent that Missling effectively admitted otherwise during an earnings

conference call on February 9, 2022. When discussing the guidance Anavex received from the FDA, Missling says "the guidance is very clear because they want to make sure that you just don't have an average statistical improvement of a certain percentage and/or score" which "doesn't mean anything to anybody." ¶83. What Missling is describing here is the precise sort of "responder analysis" that RSBQ-AUC encapsulated, *i.e.*, a measurement that provides an average statistical improvement from a summary of measurements taken over the course of the trial. *Compare* ¶55 (describing RSBQ/CGI-I) *with* ¶56 (describing RSBQ-AUC). This explains why Anavex's EXCELLENCE trial protocol on ClinicalTrials.gov showed RSBQ/CGI-I as the "primary endpoint" measure; indeed, had Anavex not identified RSBQ/CGI-I as the endpoint, the FDA would not have allowed Defendants to proceed with the trial. ¶31. Missling's description of the correct "very clear" endpoint requirement shows he knew the truth and provides yet another data point proving that RSBQ/CGI-I was always the required "primary endpoint." *See In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 73 (2d Cir. 2001) ("post-class period data may be relevant to determining what a defendant knew or should have known during the class period.").

Finally, Defendants make no attempt to square their current argument with what transpired between Missling and an investment analyst during a conference call on February 7, 2023. After more than a year of telling investors that the EXCELLENCE trial would rely on RSBQ-AUC, Missling finally reversed course in response to a line of contentious questioning from an investment analyst. ¶97. In pertinent part, the analyst asked Missling (four times in a row) to confirm whether the "FDA's input" endorsed the use of RSBQ-AUC or not. Missling never answered the question directly but instead replied that the EXCELLENCE trial would not be using RSBQ-AUC and would follow the protocol and endpoint posted on ClinicalTrials.gov, *i.e.*, RSBQ/CGI-I. ¶97. This exchange strongly supports the conclusion that the "FDA's input" was—

at all relevant times—that RSBQ/CGI-I was the required "primary endpoint" for the EXCELLENCE trial.

This leads to Defendants' next argument which is somewhat at odds with the previous one. They claim that the endpoints for the EXCELLENCE trial were "accurately and repeatedly disclosed" throughout the Class Period. Defs. Br. at 15-16. Factually, Defendants are incorrect. On several occasions Defendants contradicted themselves when describing the "primary endpoint" for the EXCELLENCE trial, including for example:

1) On February 1, 2022, when Missling said "the EXCELLENCE study will use the same endpoint" as the AVATAR trial, RSBQ-AUC (¶75);

2) On February 9, 2022, when Missling told analysts to disregard the "primary endpoint" listed on ClinicalTrials.gov, RSBQ/CGI-I, because "it will be updated when we have finalized the study outcome" (¶81);

3) On May 10, 2022, when Missling claimed that "RSBQ-AUC includes the CGI-I respond analysis . . . that is the endpoint which we will also propose for the EXCELLENCE study. That is correct. It's consistent with the AVATAR study" (¶86); and

4) On November 28, 2022, when instead of telling analysts which endpoint he was "most focused on," Missling said "both endpoints are critical" (¶89).

Even during the conference call on February 7, 2023 when Missling finally told investors and analysts that the EXCELLENCE trial would not be using RSBQ-AUC, he still refused to disavow the measure (thereby leaving open the possibility that Anavex could still use the AVATAR results to support a regulatory approval package for ANAVEX 2-73). ¶97. In fact, instead of telling analysts that they were dropping RSBQ-AUC from the EXCELLENCE trial

because the FDA would not allow it, Missling claimed they were not using the measure because "the study is large enough that it can carry the signal by itself without AUC" (meaning that Defendants did not need the extra leeway afforded by the RSBQ-AUC measure). ¶¶97, 99. They were wrong of course, as evidenced by the results when Defendants finally released them. *See* ¶¶63-65, 73 (blaming the "primary endpoint" miss on the study being "not fully powered").

Consequently, while Defendants try and claim that the "endpoints" for the EXCELLENCE trial were "accurately and repeatedly disclosed" throughout the Class Period, the facts show otherwise and by no means "discredit" the false statements "so obviously that the risk of real deception drops to nil." *See Va. Bankshares v. Sandberg*, 501 U.S. 1083, 1097 (1991); *Ganino*, 228 F.3d at 167 ("The truth-on-the-market defense is intensely fact-specific and is rarely an appropriate basis for dismissing a § 10(b) complaint for failure to plead materiality."); *Karimi v. Deutsche Bank Aktiengesellschaft*, 607 F. Supp. 3d 381, 394-95 (S.D.N.Y. 2022) (rejecting "truth-on-the-market" defense at pleading stage). To the contrary, "once a company speaks on an issue or topic, there is a duty to tell the whole truth." *Meyer v. JinkoSolar Holdings Co.*, 761 F.3d 245, 250 (2d Cir. 2014); *see also Setzer v. Omega Healthcare Inv'rs, Inc.*, 968 F.3d 204, 214 n.15 (2d Cir. 2020) ("by putting Orianna's rental payments 'in play,' Defendants were required to speak accurately and completely").

Defendants raise other arguments in support of their motion but they appear to misconstrue the crux of Plaintiff's allegations. Specifically, Plaintiff is not seeking to hold Defendants liable for some sort of failed promise to obtain FDA approval. Plaintiff does not identify any alleged false statements wherein Defendants provide any sort of estimate or assurance about the FDA approving ANAVEX 2-73. The closest Plaintiff's allegations come to that is arguably when they fault Defendants for falsely portraying the RSBQ-AUC measure as a viable "primary endpoint,"

meaning that the AVATAR trial results could potentially be used to support a regulatory approval package for ANAVEX 2-73. *See, e.g.*, ¶¶78, 92, 94. Thus, Defendants' arguments are misguided when they claim that Defendants never "promise[d] that the FDA would approve a NDA" (Defs. Br. at 11-12) or that their statements are forward-looking and therefore protected under the PSLRA's statutory safe harbor (Defs. Br. at 13-14). To be sure, none of Defendants' alleged false statements is forward-looking and whatever cautionary language Defendants rely on in no way disclosed the material adverse information they had in hand at the time, *i.e.*, RSBQ-AUC was not an acceptable endpoint. *See, e.g.*, *Meyer*, 761 F.3d at 251; *Van der Moolen Holding N.V.*, 405 F. Supp. 2d at 400 ("to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit"); *Dodona I, LLC v. Goldman, Sachs & Co.*, 847 F. Supp. 2d 624, 647 (S.D.N.Y. 2012) (rejecting "boilerplate disclosures" because "generic risk disclosures are inadequate to shield defendants from liability for failing to disclose known specific risks").

B. Plaintiff Adequately Pleads a Strong Inference of Scienter.

To plead scienter, Plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Novak*, 216 F.3d at 315. Courts must conduct the scienter analysis "holistically" to determine "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter[.]" *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007). "In this Circuit, plaintiffs can satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *Setzer*, 968 F.3d 204 at 212. Scienter is alleged if a "reasonable person would deem the inference of scienter…at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324-26. The inference "need not be irrefutable, *i.e.*, of the smoking-

gun genre, or even the most plausible of competing inferences;" rather, the inference of scienter need only be ***equally plausible*** as any non-culpable inference. *Id*. at 324. If the inferences for and against scienter are in "equipoise," the complaint survives. *Id.* at 331.

Plaintiff sufficiently alleges both motive and opportunity as well as strong circumstantial evidence of conscious misbehavior or recklessness by showing that "[D]efendants (1) benefitted in a concrete and personal way from the purported fraud; (2) engaged in deliberately illegal behavior; (3) knew facts or had access to information suggesting that their public statements were not accurate; or (4) failed to check information they had a duty to monitor." *Blanford,* 794 F.3d at 306. Where a plaintiff alleges defendants "had knowledge of facts . . . that explicitly contradicted their public statements . . . [t]hese allegations alone are enough to satisfy the pleading requirement for scienter." *Heller v. Goldin Restructuring Fund, L.P.*, 590 F. Supp. 2d 603, 622 (S.D.N.Y. 2008). Indeed, Defendants knew RSBQ-AUC was not acceptable because the FDA had instructed them to use RSBQ/CGI-I as the "primary endpoint" for its clinical trial studies. ¶¶58-59. *See Scholastic Corp.*, 252 F.3d at 76 ("access to non-public information contradicting" statements supports scienter). Communications between Defendants and the FDA began between December 2017 and February 2018 (¶59) and continued thereafter as ANAVEX 2-73 received approval for the Phase 2, AVATAR, and EXCELLECNE trials prior to their commencement in March, June, and September 2019, respectively (¶58). The FDA would have reiterated the RSBQ/CGI-I requirement when meeting with Anavex to discuss Fast Track Status in February 2020 and again when meeting to discuss the trial designs and regulatory approval packages in February 2023. ¶58. By regulation, Anavex received "intensive guidance" for its "drug development program." ¶59 (citing 21 C.F.R. 312.22 and FDA Guidance). This is powerful evidence of scienter that courts routinely credit in sustaining scienter allegations. *E.g.*, *Christine Asia*, 718 F. App'x at 22-23

(scienter where executives met with government officials and discussed relevant information); *Karimi*, 607 F. Supp. 3d at 397-98 ("[W]arnings from" regulators are "widely recognized to be evidence of scienter.").

Missling's scienter is bolstered by the frequency with which he spoke about the competing endpoints. While at times attempting to evade questions (¶107), he also openly admitted that "the guidelines of the FDA guidance are really specific," that "the FDA guidelines really explicitly say, please use this anchor-based method," and that "the guidance is very clear." ¶83. Missling was also the primary speaker on behalf of Anavex when it came to discussing the endpoints for Defendants' clinical trials. ¶105. Investors are entitled to assume that executives are informed about the topics on which they publicly speak. *See Strougo v. Barclays PLC*, 105 F. Supp. 3d 330, 351 (S.D.N.Y. 2015) (scienter where defendant "held himself out to the public as intimately knowledgeable"); *accord In re MBIA, Inc., Sec. Litig.*, 700 F. Supp. 2d 566, 591 (S.D.N.Y. 2010). Further, the inference of scienter is especially compelling here because the EXCELLENCE trial's "primary endpoint" was the subject of intense scrutiny. *New Orleans Emps. Ret. Sys. v. Celestica, Inc.*, 455 F. App'x 10, 14 & n.3 (2d Cir. 2011) (scienter where issue was one "about which investors and analysts often inquired"); *see also Reese v. Malone*, 747 F.3d 557, 571 (9th Cir. 2014), *overruled on other grounds by City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605 (9th Cir. 2017) (issue was "the focus of both public and government inquiries").

The importance of the EXCELLENCE trial and, in turn, ANAVEX 2-73's ability to obtain regulatory approval and generate revenue also support Plaintiff's theory of scienter. ¶106. Without any other way to generate revenue, Anavex was forced to rely on private placements and at-the-market offerings to raise capital. ¶108. Consequently, maintaining an inflated stock price was

mission critical to keeping the lights on at the company and ensuring Missling could pay himself. ¶108. This could only be accomplished if investors believed the FDA would be willing to accept RSBQ-AUC as part of the regulatory approval package, and Missling went to great lengths to maintain that farce. This included inexplicably delaying the reporting of trial results by several months for both the AVATAR and EXCELLENCE trials (¶¶109-10), providing "spin" and "ad hoc" analyses to cover up weak study results (¶111), and issuing gratuitous off-topic press releases to pump Anavex's stock price on the eve of adverse public disclosures to help protect the stock price (¶¶112-13). The truth about the RSBQ-AUC data (*i.e.*, the FDA would not accept it) was in many ways the "sin[e] qua non" behind Anavex's ability to survive. *See Skiadas*, 2020 U.S. Dist. LEXIS 105814, at *32; *In re Avon Sec. Litig.*, No. 19-cv-01420 (CM), 2019 U.S. Dist. LEXIS 200816, at *62 (S.D.N.Y. Nov. 18, 2019) (scienter adequately pleaded where "it would be absurd to suggest that Avon's senior management was unaware of a widespread delinquency problem in the company's single largest market"); *In re GE Sec. Litig.*, 857 F. Supp. 2d 367, 395 (S.D.N.Y. 2012) (applying core operations where "GE Capital provided 50% of GE's revenues"); *see also Constr. Indus. & Laborers Joint Pension Tr. v. Carbonite, Inc.*, 22 F.4th 1, 9 (1st Cir. 2021) ("defendants 'must have known that [product] was not functional,' because the product's professed importance to the company strongly implied that senior officers at the company were following it closely and thus were aware of its failings").

Plaintiff's allegations of scienter are certainly "cogent and at least as compelling as any opposing inference," which is all that is required at the pleading stage. *Tellabs*, 551 U.S. at 322-23; *Altimeo Asset Mgmt.*, 19 F.4th at 150 (warning courts not to "mistake heightened pleading standards for impossible ones"). Indeed, Plaintiff's inference of scienter easily outweighs Defendants' proposed nonculpable explanation, *i.e.*, "the FDA did not tell Anavex that it needed

to only use a certain type of endpoint and that Anavex adjusted the study design during the Class Period as disclosed." Defs. Br. at 21. But at the pleading stage, Defendants' "supposed evidence of good faith is just as likely to show bad faith or not to be especially probative at all." *Stadium Capital LLC v. Co-Diagnostics, Inc.*, No. 22-cv-6978 (AS), 2024 U.S. Dist. LEXIS 19754, *23 (S.D.N.Y. Feb. 5, 2024). This is especially true considering that Anavex was told (repeatedly) about the "primary endpoint" it needed to use (RSBQ/CGI-I) and that Missling did not adjust the study design during the Class Period according to ClinicalTrials.gov (but instead just revealed that they would not be able to rely on RSBQ-AUC data). *See* ¶¶58-59, 97.[3]

C. Plaintiff Adequately Pleads Loss Causation.

"Allegations of loss causation, are evaluated under the notice pleading standard in Federal Rule of Civil Procedure Rule 8." *See In re Fairway Grp. Holding Corp. Sec. Litig.*, No. 14-cv-0950, 2015 U.S. Dist. LEXIS 5999, at *43 (S.D.N.Y. Jan. 20, 2015); *see also Gormley v. Magicjack Vocaltec Ltd.*, 220 F. Supp. 3d 510, 517 (S.D.N.Y. 2016) ("Pleading loss causation with particularity is not required"). Thus, Plaintiff's burden of pleading loss causation is "not a heavy one," and the complaint "must simply give Defendants 'some indication' of the actual loss suffered and of a plausible causal link between the loss and the alleged misrepresentations." *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 187 (2d Cir. 2015). "Generally,

[3] Defendants' argument is also undercut by FDA Guidance holding that sponsors are subject to civil money penalties for posting inaccurate information to ClinicalTrials.gov. The guidance document makes clear that Section 303(f)(3) of the Federal Food, Drug, and Cosmetic Act authorizes the FDA to "assess civil money penalties" against sponsors who fail to submit required "clinical trial information" to the website, such as the "study design" (which includes the study's "primary endpoint" measurement). *See* U.S. FOOD & DRUG ADMIN., CIVIL MONEY PENALTIES RELATING TO THE CLINICALTRIALS.GOV DATA BANK: GUIDANCE FOR RESPONSIBLE PARTIES, SUBMITTERS OF CERTAIN APPLICATIONS AND SUBMISSIONS TO FDA, AND FDA STAFF (2020). To accept Defendants' competing explanation means that they knowingly violated federal regulations by posting inaccurate "clinical trial information" to ClinicalTrials.gov.

plaintiffs sufficiently plead loss causation when they allege that their share's 'price fell significantly after the truth became known' through an express, corrective disclosure or 'through events constructively disclosing the fraud' like the 'materialization of [the] risk' concealed." *Abramson v. NewLink Genetics Corp.*, 965 F.3d 165, 179 (2d Cir. 2020) (citing *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 262 (2d Cir. 2016)).

Defendants lied about the "primary endpoint" they would be able to potentially use in connection with a regulatory approval package from ANAVEX 2-73. This allowed them to discuss trial data through the lens of an RSBQ-AUC analysis which, in turn, masked the true weakness of the trial data. ¶115. On February 7, 2023, when Missling reluctantly revealed that the EXCELLENCE trial would not be using RSBQ-AUC (while at the same time continuing to lie about why), investors started to develop concerns over the strength and reliability of the previous study's results, *i.e.*, the AVATAR trial that had used RSBQ-AUC. ¶115. These concerns translated into a sharp decline in the price of Anavex's stock (<11.5%). ¶115. On January 2, 2024, Defendants reported the EXCELLENCE trial results and revealed that ANAVEX 2-73 failed to show statistical significance under the FDA-approved RSBQ/CGI-I endpoint. ¶116. For analysts and investors who had been following the stock, this confirmed for them that Anavex's trial data was never as strong or positive as Defendants had previously represented and the future for ANAVEX 2-73 was much riskier than initially believed (given that any additional studies would now have to use the more rigorous RSBQ/CGI-I measurement). ¶116.

Plaintiff's theory of loss causation is well-supported by the case law. For example, in *Abramson*, *supra*, the court endorsed a loss causation theory similar to the one at bar. In that case, the plaintiff argued that the defendants caused his losses by concealing GCP violations that occurred during a Phase 3 clinical trial. The court held that the violations "foreseeable caused the

failure of the Phase 3 trial" and that "[t]his suffices because, at this early pleading stage, we do not require 'conclusive proof' of the causal link between the fraud and Plaintiffs' loss." *Id*. at 178-80. As demonstrated by *Abramson*, loss causation is adequately alleged at the pleading stage so long as the subject matter of the lie relates in some part to the events that ultimately precipitate the stock market decline; that is the case here where Defendants used various tactics to keep secret the strength (or weakness) of the trial data they had collected to date and investors only came to find out once Anavex was forced to present data using the correct "primary endpoint" measure, *i.e.*, RSBQ/CGI-I. *See* ¶¶70-73 (analysts questioning the totality of trial data in response to the EXCELLENCE results and prospects for filing approval package for ANAVEX 2-73).

Defendants' disclosures on both February 7, 2023 and January 2, 2024 contained new material information that prompted material declines in the price of Anavex's stock. *See* ¶¶115-16. Defendants try to dispute this point by limiting the market response (or corrective window) to the day the news emerged, *i.e.*, February 7, 2023. Defs. Br. at 23. But the law does not support their argument. "A two- to three-day window" is "common" when evaluating whether news moved a stock price. *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 310 F.R.D. 69, 96 (S.D.N.Y. 2015) (rejecting attack on market efficiency expert report "[b]ecause it is standard for experts to utilize an event window including both the day of the event and the day following an event"); *see also AP-Fonden v. GE*, No. 17-CV-8457 (JMF), 2023 U.S. Dist. LEXIS 174168, *57 (S.D.N.Y. Sep. 28, 2023) (allowing "three-day window" for event study analysis); *Swanson v. Interface, Inc.*, No. 20-CV-5518 (BMC), 2022 U.S. Dist. LEXIS 100506, *8 (E.D.N.Y. June 5, 2022) ("not fatal to plaintiff's case" where stock fell "one day" after SEC announcement). A decline in stock price in response to news constitutes *prima facie* evidence that the news was previously unknown to the market. *See Lea v. TAL Educ. Grp.*, 837 F. App'x 20, 28 (2d Cir. 2020)

("the stock value loss following the disclosure of such information in the Muddy Waters report is sufficient at this stage to plead loss causation as to each of the claims"); *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 233-34 (2d Cir. 2014) (where plaintiffs alleged that settlement agreements revealed misrepresentations about the company's financial condition, and that "the market reacted negatively to the . . . corrective disclosure by a significant (12%) decline in [defendant's] stock"); *Ganino*, 228 F.3d at 167-68 (movement of stock in response to corrective disclosure demonstrates materiality of new information).

Concerning the January 2, 2024 corrective disclosure, Defendants argue that it was merely investor "disappointment" with the trial results that brought Anavex's stock price down. Defs. Br. at 24. However, as demonstrated with *Abramson*, the negative results were sufficiently related to the alleged fraud to qualify as a "corrective disclosure." *Id.* at 180. Moreover, while Defendants contest the reasons for the decline, they have not identified any other news unrelated to the alleged fraud here that caused the stock drop, and in any event, such an inquiry into possible confounding factors is "not to be decided on a Rule 12(b)(6) motion to dismiss." *Fin. Guar. Ins. Co. v. Putnam Advisory Co., LLC*, 783 F.3d 395, 404-05 (2d Cir. 2015).

D. Missling Is Liable as a "Control Person" under Section 20(a).

Plaintiff has adequately pleaded an underlying primary violation, as discussed above. Thus, Defendants' motion to dismiss Plaintiff's "control person" claim should be denied. *See Altimeo Asset Mgmt.*, 19 F.4th at 152.

V. CONCLUSION

Plaintiff respectfully requests that the Court deny Defendants' motion in its entirety.[4]

[4] In the event that the Court is inclined to grant any aspect of Defendants' motion, Plaintiff respectfully requests leave to file an amended complaint to address any deficiencies in the current allegations. *See Loreley*, 797 F.3d at 191.

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